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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/525,567 | 02/25/2005 | Iwao Okamoto | OKAMOTO11 | 3039 |

1444 7590 11/15/2006

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| EXAMINER | |
|---|---|
| ROOKE, AGNES BEATA | |
| ART UNIT | PAPER NUMBER |
| 1656 | |

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/525,567 | OKAMOTO ET AL. | |
| | Examiner | Art Unit | |
| | Agnes B. Rooke | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,6,8 and 10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1, 11-13* is/are allowed.

6)☒ Claim(s) *6,8 and 10* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This final office action is in response to the paper filed on 8/22/2006.

Claims 1, 6, 8, and 10-14 are pending and under examination. Claims 2-5, 7, and 9 are cancelled. Claim 14 is added as a new claim.

### *Priority*

This application is a 371 of PCT/JP03/10795 filed on 08/26/2003.

***All Rejections and Objections not present in this office action have been withdrawn.***

### ***Rejections withdrawn***:

1. The rejections of claims 1-5 and 6, 7, under 35 U.S.C. 101, are withdrawn in view of the amendments.

2. The rejections of claims 1, 2, 5-13, under 35 U.S.C., second paragraph, are withdrawn in view of the amendments.

3. The rejections of claims 1-13, under 35 U.S.C., first paragraph, are withdrawn in view of the amendments.

4. The rejections of claims 1-10 and 13, under 35 U.S.C. paragraph 102 (b) by Katoka et al. are withdrawn in view of the amendments.

5. The rejection of claims 1-11 and 13, under 35 U.S.C. paragraph 102(b) by Oka et al and claims 1 and 12 by Yamada et al. are withdrawn in view of the amendments.

Applicants responded to the rejections under 35 U.S.C. 102(b) by stating that none of cited references discloses or suggests a purified anti-allergic royal jelly protein as defined in claim 1; and that none of the references discloses or suggests a method for treating or preventing allergic diseases by administering to a patient an effective amount of anti-allergic royal jelly protein.

Examiner responds that the rejections under 35 U.S.C. 102(b) are withdrawn, however new rejections under 35 U.S.C. 103(a) necessitated by amendments are in place. Please see below.

***Rejections maintained and new rejections necessitated by amendments***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over prior art discussed in the Applicants' specification (pages 6-7 referring to the article of Schimitzova et al., *A Family of major royal jelly proteins of the honeybee Apis mellifera L.*, CMLS Cell. Mol. Life. Sci. (1998), 1020-1030, see page 7 of the specification, lines 12-25) in view of Oka et al., *Suppression of allergic reactions by royal jelly in association with the restoration of macrophage function and the*

*improvement of Th1/Th2 cell responses, International Immunopharmacology,* 1, 2001, p. 5212-532.

The Applicants clearly acknowledge on pages 6 and 7 of the specification that royal proteins of SEQ ID NOs:1 and 2 of the instant invention are known in the prior art. On page 7, lines 12-25 of the specification, Applicants state the major royal jelly proteins MRJP1 (which is instant SEQ ID NO:2 having molecular weight of about 55kDa) and MRJP3 (which is instant SEQ ID NO:1 having molecular weight of about 70 kDA), are disclosed by Schimitzova et al; see lines 24-25; where RJP70 and RJP55 are possibly substantially the same proteins as known MRJP3 (70 kDA protein) and MRJP1 (55 kDa protein).

Therefore, examiner acknowledges that SEQ ID NO:1 has molecular weight of 70 kDA and it is known in the prior art as MRJP3, and SEQ ID NO:2 has molecular weight of 55kDa and it is known in the prior art as MRJP1. See the specification, pages 6 and 7.

The prior art presented by Applicants in the reference to Schimitzova et al. does not teach oral administration of the royal jelly proteins.

Oka et al. teach in the Abstract that oral administration of royal jelly (RJ) to immunized mice significantly decreased the serum levels of antigen-specific Ig E and hypersensitivity reactions of ear skin; where the results suggested that RJ suppressed antigen-specific Ig E production and histamine release from mast cells in association

with the restoration of macrophage function. See also Figure 1 and Figure 2, page 524, where RJ was administered orally. Further, oral administration of royal jelly (1g/kg) to mice was discussed. See Abstract or Figures 6 or 7.

Further, on page 531, right column, it states that demonstrated that royal jelly suppresses histamine release from mast cells, and that royal jelly has immunomodulatory activities that may be useful for preventing the onset of allergies or alleviating allergic symptoms.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a royal jelly composition composed of SEQ ID NOs: 1 and 2, since these sequences are commonly known in the art as MRJP1 or MRJP3, as it is disclosed by Applicants in the specification in reference to Schimitzova et al. and then design a method of oral administration of these royal jelly proteins to a mammal as discussed by Oka et al. to treat allergic reactions and prevent or alleviate allergic symptoms.

One would be motivated to design such a composition and a method of administration as claimed because royal jelly proteins are known in the art and are known to be used to treat allergic diseases.

## ***Objections***

Claim 14 is objected to because it depends from rejected independent claim 6.

Prior art of interest:

1. "Benefits of Royal Jelly"- research finds updated on Feb 16, 2006 (as attached pages 1-3).

2. "Royal Jelly Proteins as a Tool for Development of Functional Ingredients for Health"- Standing Commission of Apitherapy (as attached pages 1-5).

***Conclusion***

According to the SCORE search SEQ ID NOs:3 and 4 are novel. Therefore, no rejection under 35 U.S.C. 103(a) would apply.

Claims 1 and 11-13 are allowable.

Claim 14 is objected to because it depends from rejected claim 6.

Claims 6, 8, and 10 are not allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

ROBERT A. WAX
PRIMARY EXAMINER